CssBA01 Recruitment Script/Email

Title:

A Phase 1 Dose Escalating Study of a Prototype CS6 Subunit Vaccine with a Modified Heat-labile Enterotoxin from Enterotoxigenic *Escherichia coli* (ETEC)

What is this study about?

In this study, we are testing a vaccine against enterotoxigenic *Escherichia coli* (ETEC), a bacterium that causes traveler's diarrhea. The vaccine is given by a shot into the muscle or skin of your upper arm. There are three components to the vaccine. Subjects will receive three injections of one component or a combination of the components:

- CssBA alone
- dmLT alone
- CssBA + dmLT

These are investigational products, meaning that they are still being tested and have not been approved for sale in the United States by the U.S. Food and Drug Administration. This is the first time that the vaccine components have been given to humans.

Our main study goals are:

1. To test safety of increasing doses of the vaccine given in the muscle
2. Evaluate immune (infection fighting ability) responses after vaccination and compare immune responses between groups that received the different vaccine doses
3. Identify a safe and immunogenic dose of the vaccine to be used in future studies of the vaccine.

What is ETEC?

ETEC is one of the most common causes of travelers' diarrhea, and infection can occur after eating or drinking contaminated food or water. The military is involved in developing a vaccine because soldiers are frequently sent to areas where they may be exposed to ETEC.

What is required to participate in this study?

In order to qualify, you must meet all of the following eligibility criteria:

- Healthy adult between the ages of 18 and 45
- Sign the written informed consent document
- Pass a written test of understanding and comprehension (70% or greater correct)
- Able to come to all clinic visits
- Women cannot be pregnant or nursing and must agree to use effective and reliable birth control methods throughout the study. You should avoid pregnancy or breastfeeding for 3 months after last vaccine dose.

You will not be able to participate if you have:

- Been previously exposed to ETEC bacteria in the past three years, such as a past infection, an earlier research study, or through your work
- A positive blood test for Hepatitis B, Hepatitis C, or HIV (the virus that causes AIDS)
- Abnormal clinical laboratory results
- Taken another experimental product within 30 days of first vaccination
- Certain chronic skin diseases or active skin infection
- Abnormal bowel habits (fewer than 3 per week or more than 3 loose stools per day)
- A condition that requires the use of immunosuppressant drugs such as corticosteroids or chemotherapy
- Regular use of constipation, antacid, or anti-diarrhea medications

How long is the study?

Clinic visits will occur over about 3 months, and then you will receive telephone call follow-ups at 6 months and one year.

How will I be compensated?

If you are eligible and choose to participate, you may receive up to $1,475 for study participation.

What happens during the screening visit?

The screening visit will include medical history, physical examination with vital signs (blood pressure, pulse, and temperature) and weight, and blood tests. You will be asked to give about 1 tablespoon of blood. You will also be asked to report any medications, including over the counter medications and contraceptives that you are currently taking and have taken recently. Females will be given urine pregnancy tests performed at screening and just prior to vaccinations.

What happens during the pre-vaccination visit?

The pre-vaccination visit will include a brief physical examination with vital signs (blood pressure, pulse, and temperature) and weight, and blood tests. You will be asked to give less than 2 tablespoons of blood. During this visit, blood tests for HIV (the virus that causes AIDS), and Hepatitis B and C will be performed. You must have a negative test for these to participate in the study.

What happens during the study period?

If you are eligible and decide to participate, you will be put into a group to receive one or a combination of the vaccine components. The time of your clinic visits for vaccination will be about 1 and ½ to 2 hours. You will receive a vaccine shot on Day 0, Day 21, and Day 42. The

vaccine will be given as a shot into the muscle of your upper arm. You will have your vital signs taken before each shot and after a 30 minute observation period following vaccination. You will be asked to return to the clinic on Days 1, 7, 22, 28, 43, 49, 56, and 70. You will have telephone follow-up calls on Days 180 and 360. The duration of clinic follow-up visits will be about 30-45 minutes. The follow-up telephone calls will take about 5-10 minutes.

What should I expect after vaccination?

After injection, pain, tenderness, swelling, redness, or bruising may occur at the injection site. An allergy to the vaccine is also possible. An allergic reaction could include skin rash, difficulty breathing or wheezing, a sudden drop in blood pressure, fast pulse, swelling around the mouth, throat, or eyes, and sweating. An allergic reaction may be life threatening. Because of these possible reactions, you will be closely monitored after each shot.

How do I schedule a visit and find out more information?

Please call the Clinical Trials Center using the contact information below and provide the following information to the staff:

- Name
- Date of birth
- Gender
- Address
- Phone number

Department of Clinical Trials, 6:30 am- 2:30 pm,
Monday-Friday at 301-319-9320

You may have your information stored in a database if you wish to be contacted for future studies.